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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,378	11/25/2003	Geoffrey D. Block	4149-032329	4630

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,378	BLOCK, GEOFFREY D.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-43* is/are pending in the application.

4a) Of the above claim(s) *39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0804*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I, claims 26-38, in the reply filed on February 18, 2005 is acknowledged. Claims 26-38 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-31, and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-31 and 33-35 are rendered vague and indefinite because the limitations recited therein lack adequate antecedent basis because they are outside the limitations of claim 26 (from which these claims directly or indirectly depend). That is, claim 26 (as well as claims 27, 32, and 36-38) is drawn to cultured pancreatic islet cells, *per se*. Please note that the product defined by claim 26 (as well as claims 27, 32, and 36-38), once removed from the culture medium, is pancreatic cells (not altered cells, not less differentiated cells, not tissue structures within matrices, etc). However, claims 28-31 and 33-35 are drawn to altered pancreatic cells produced by post-culturing steps – e.g., claim 28 recites a post-culturing method involving altering the phenotype of the pancreatic islet cells, claim 29 recites a post-culturing method involving preparing a less-differentiated state of such cells, and claim 33 recites a post-culturing step involving the formation of tissue structures within a matrix – none of which properly read upon the pancreatic cells defined by claim 26. In other words, each of the products produced by the

post-cultural steps of claims 28-31 and 33-35 do not properly define the pancreatic cells of claim 26 (they instead define different cellular/tissue products). As such, these claims lack antecedent basis as they do not properly read upon the pancreatic islet cells defined by claim 26. It is suggested that these claims be cancelled in response to this Office action.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Archer et al. (US 4,439,521), over Beattie et al. (US 5,116,753), over Hellerstrom et al. (Diabetes, 1980), over Meda et al. (Diabetes, 1980), or over Takaki et al. (Proc. Exp. Biol. Med., 1975); and under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rubin et al. (US 5,587,309) or over Brothers (US 5,928,942).

Pancreatic islet cells (prepared *in vitro*) are claimed.

Each of the cited references teach pancreatic islet cells prepared *in vitro*, as well as pharmaceutical preparations thereof (e.g., isolated cells, and/or within fluid media, conducive for transplantation/implantation) which appear to anticipate the claimed pancreatic islet cells - see entire documents (please note that the limitations set forth in claims 28-31 and 33-35 have not been afforded patentable weight as they are outside the limitations of claim 26 - see USC 112, second paragraph rejection above). In other words, the instantly claimed pancreatic islet cells (once removed from the recited *in vitro* culture medium) are still pancreatic cells, which are patentably no different from any of the cited prior art pancreatic islet cells (once removed from their respective culture/maintenance media).

In the alternative, even if the claimed pancreatic islet cells are not identical to the referenced pancreatic islet cells with regard to some unidentified characteristics, the differences between that which is disclosed (see, e.g., page 13, lines 26-31, of the instant specification which briefly mentions pancreatic islet cells) and that which is claimed are considered to be so slight that the referenced pancreatic islet cells are likely to inherently possess the same characteristics of the claimed pancreatic islet cells, particularly since all are drawn to pancreatic islet cells prepared *in vitro*. Thus, the claimed pancreatic islet cells would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by each of the cited references, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1654